Premarket Notification [510(k)] Summary

ASSIST Header Cleaner™

Submitter's Name: Alcavis International
Address: 8 - 8 Metropolitan Court
Gaithersburg, MD 20878
Phone number: (301) 330-7597
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Contact Name: Mr. Gary J. Mishkin
Vice President, Research and Development

Date Summary Prepared: November 8, 2004

Device Trade Name: ASSIST Header Cleaner™
Common Name: Dialyzer Reprocessing System

Substantially Equivalent Device: RenaClear® Dialyzer Cleaning System (K991851)

A. Device Description

The ASSIST Header Cleaner™ is a one-piece device used to assist with the manual cleaning of headers in reusable hemodialyzers. One end of the ASSIST unit is inserted and attached to the arterial blood port on the header cap. The other end of the ASSIST unit is connected to a supply of reverse osmosis water. Jets of RO water are sprayed inside of the header to break up and clear away any debris, including clotted blood, in the header space. The dialyzer is manually turned along its longitudinal axis during this process to allow the water jets to contact all side surfaces of the header. This operation is repeated on the venous end where, besides cleaning, the water is used to flush the blood/debris/water mixture from the arterial end of the dialyzer. The dialyzer is flipped again and the process is repeated for a second time at the arterial end to flush away any blood/debris/water mixture from the venous end of the dialyzer.

B. Intended Use

In the clinical setting, to clean residual blood and other debris from the headers, header spaces and the insides of header caps of multiple-use hemodialyzers prior to an approved reprocessing process for hemodialyzers

C. Comparison of Technological Characteristics to Substantial Equivalent Device:

The ASSIST Header Cleaner™ is a manual device which uses reverse osmosis water to clean hemodialyzers. The RenaClear® Dialyzer Cleaning System (K991851) is an automated, software controlled, electrically powered device which uses water, a disinfectant, and air pressure to clean both the headers and membrane fibers of hemodialyzers. Both devices are used to preclean reusable hemodialyzers before further processing and testing the hemodialyzers on dialyzer reprocessing machines.

D. Testing:

Tests have been performed which demonstrate the ASSIST Header Cleaner™ is safe and effective, and performs as intended without adversely affecting the hemodialyzer being cleaned. The materials used in the ASSIST Header Cleaner™ are compatible for its intended use.

E. Summary

When used as indicated in the Directions for Use, the ASSIST Header Cleaner™ is as safe and effective as other dialyzer cleaning systems currently in use in the United States.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB - 3 2005

Mr. Gary J. Mishkin
Vice President, Research and Development
ALCAVIS International
8-8 Metropolitan Court
GAITHERSBURG MD 20878

Re: K043126
Trade/Device Name: Alcavis ASSIST Header Cleaner™
Regulation Number: None
Regulatory Class: Unclassified
Product Code: 78 LIF
Dated: November 8, 2004
Received: November 12, 2004

Dear Mr. Mishkin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K043126

Device Name: **ASSIST Header Cleaner™**

Indications for Use:

To aid in the cleaning of the headers, header spaces, and header caps of multiple-use hemodialyzers prior to an approved reprocessing procedure for reusable hemodialyzers.

Prescription Use __X__ AND/OR Over the Counter Use ____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Seymour

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K043126